K113437

510(k) SUMMARY

AUG 6 2012

510(k) Owner:	Alfa Wassermann Diagnostic Technologies, LLC 4 Henderson Drive West Caldwell, NJ 07006 Contact: Hyman Katz, Ph.D. Phone: 973-852-0158 Fax: 973-852-0237	
Date Summary Prepared:	November 18, 2011	
Device:	Trade Name:	ACE Axcel Clinical Chemistry System
	Classification:	Class 1
	Common/Classification Name:	Analyzer, Chemistry (Photometric, Discrete), For Clinical Use (21 C.F.R. § 862.2610) Product Code JJE
	Trade Name:	ACE Hemoglobin A1c (HbA1c) Reagent
	Classification:	Class 2
	Common/Classification Name:	Assay, Glycosylated Hemoglobin (21 C.F.R. § 864.7470) Product Code LCP
	Trade Name:	ACE CEDIA T Uptake Reagent
	Classification:	Class 2
	Common/Classification Name:	Radioassay, Triiodothyronine Uptake (21 C.F.R. § 862.1715) Product Code KHQ
	Trade Name:	ACE T4 Reagent
	Classification:	Class 2
	Common/Classification Name:	Enzyme Immunoassay, Non-Radiolabeled, Total Thyroxine (21 C.F.R. § 862.1700) Product Code KLI

	Trade Name:	ACE Ferritin Reagent
	Classification:	Class 2
	Common/Classification Name:	Ferritin, Antigen, Antiserum, Control (21 C.F.R. § 866.5340) Product Code DBF
Predicate Devices:	Manufacturer for analyzer/reagent system predicate: Alfa Wassermann ACE Clinical Chemistry System (K931786) ACE Reagents (K063306, K981375, K981377 and K050944)	
Device Descriptions:	The ACE Axcel Clinical Chemistry System consists of two major components, the chemistry instrument and an integrated Panel PC. The instrument accepts the physical patient samples, performs the appropriate optical or potentiometric measurements on those samples and communicates that data to an integral Panel PC. The Panel PC uses keyboard or touch screen input to manually enter a variety of data, control and accept data from the instrument, manage and maintain system information and generate reports relative to patient status and instrument performance. The Panel PC also allows remote download of patient requisitions and upload of patient results via a standard interface. Prior to the ACE Hemoglobin A1c (HbA1c) Reagent assay, whole blood samples require a pretreatment step, which is done on-board the analyzer. The red blood cells in the sample are lysed by the Hemoglobin Denaturant and the hemoglobin chains are hydrolyzed. For determination of HbA1c, a latex agglutination inhibition assay is used. In the absence of HbA1c in the sample, the agglutinator (synthetic polymer containing the immunoreactive portion of HbA1c) in the HbA1c Agglutinator Reagent and the antibody-coated microparticles in the HbA1c Antibody Reagent will agglutinate. The presence of HbA1c in the sample competes for the antibody binding sites and inhibits agglutination. The increase in absorbance, monitored monochromatically at 592 nm, is inversely proportional to the HbA1c present in the sample. For the determination of total hemoglobin, all hemoglobin derivatives in the sample are converted to alkaline hematin. The reaction produces a green colored solution, which is measured bichromatically at 573 nm/692 nm. The intensity of color produced is directly proportional to the total hemoglobin concentration in the sample. The concentrations of both HbA1c and total hemoglobin are measured, the ratio is calculated and the result reported as percent HbA1c. The CEDIA T Uptake assay uses recombinant DNA technology to produce a unique homogeneous enzyme immunoassay system. The assay is based the bacterial enzyme β-galactosidase, which has been genetically engineered into two inactive fragments. These fragments spontaneously re-associate to form fully active enzyme which, in the assay format, cleaves a substrate, generating a color change that can be measured spectrophotometrically. In the assay, enzyme donor thyroxine conjugate binds directly to the unoccupied thyroxine-binding sites in the sample, preventing the spontaneous re-association of the	

	enzyme fragments to form the active enzyme. Thus, thyroxine-binding proteins regulate the amount of β-galactosidase formed from the reassembly of the remaining donor and enzyme acceptor as monitored by the hydrolysis of the substrate o-nitrophenyl-β-galactopyranoside. The ACE T4 Assay is a homogeneous enzyme immunoassay using ready-to-use liquid ACE T4 Reagent. The assay uses 8-anilino-1-naphthalene sulfonic acid (ANS) to dissociate thyroxine from the plasma binding proteins. Using specific antibodies to thyroxine, this assay is based on the competition of glucose-6-phosphate dehydrogenase (G6PD) labeled thyroxine and the dissociated thyroxine in the sample for a fixed amount of specific antibody binding sites. In the absence of thyroxine from the sample, the thyroxine labeled G6PD in the second reagent is bound by the specific antibody in the first reagent, inhibiting the enzyme's activity. The enzyme G6PD catalyzes the oxidation of glucose-6-phosphate (G6P) with nicotinamide adenine dinucleotide (NAD^+) to form 6-phosphogluconate and reduced nicotinamide adenine dinucleotide (NADH). NADH strongly absorbs at 340 nm whereas NAD^+ does not. The rate of conversion, determined by measuring the increase in absorbance bichromatically at 340 nm/505 nm during a fixed time interval, is directly proportional to the amount of thyroxine in the sample. The concentration of thyroxine is determined automatically by the ACE Clinical Chemistry System using a logarithmic calibration curve established with calibrators, which are provided separately. In the Ferritin Assay, serum ferritin, in the presence of anti-ferritin conjugated latex micorparticles, and a buffer promoting aggregation, initiates an antigen-antibody reaction, resulting in the agglutination of the latex microparticles. The agglutination is detected turbidometrically by an absorbance change measured at a wavelength of 592 nm. The magnitude of the absorbance change is proportional to the ferritin concentration in the sample.
Intended Use:	Indications for Use: The ACE Axcel Clinical Chemistry System is an automated, discrete, bench-top, random access analyzer that is intended for *in vitro* diagnostic use in the quantitative determination of constituents in blood and other fluids. ACE Hemoglobin A1c (HbA1c) Reagent is intended for the quantitative determination of hemoglobin A1c (μmol/L) and total hemoglobin (g/dL) in human EDTA whole blood for the calculation of percent hemoglobin A1c using the ACE Axcel Clinical Chemistry System. The test is intended for use in clinical laboratories or physician office laboratories to monitor long term blood glucose control in individuals with diabetes mellitus. For *in vitro* diagnostic use only. The ACE CEDIA T Uptake homogenous enzyme immunoassay is intended for the quantitative determination of unoccupied binding sties of thyroxine-binding proteins in serum using the ACE Axcel Clinical Chemistry System.

	Measurements of triiodothyronine uptake are used in the diagnosis and treatment of thyroid disorders. This test is intended for use in clinical laboratories or physician office laboratories. For in vitro diagnostic use only. The ACE T4 Reagent is intended for the quantitative determination of total thyroxine (T4) concentration in serum using the ACE Axcel Clinical Chemistry System. Total thyroxine measurements are used in the diagnosis and treatment of thyroid diseases. This test is intended for use in clinical laboratories or physician office laboratories. For in vitro diagnostic use only. The ACE Ferritin Reagent is intended for the quantitative determination of ferritin concentration in serum using the ACE Axcel Clinical Chemistry System. Measurements of ferritin aid in the diagnosis of diseases affecting iron metabolism, such as hemochromatosis (iron overload) and iron deficiency anemia. This test is intended for use in clinical laboratories or physician office laboratories. For in vitro diagnostic use only.
Technological Characteristics:	The following is a description of the major features of the ACE Axcel Clinical Chemistry System: • System throughput is approximately 160 test results per hour for routine, single reagent chemistries. System throughput will be higher when the test workload includes ISE's. • The instrument has a capacity of 40 reagent containers on board. A reagent cooling system maintains the reagents at 12°C during instrument operation. • Reagent containers are identified by computer coded labels to simplify system operation. All reagents in the system must include an identification label on the container. • Sample and reagent sensing notify the operator of a depleted condition during operation. • The system performs analysis at a reaction temperature of 37°C. • An electrolyte subsystem capable of measuring sodium, potassium and chloride concentrations is included. • Primary draw tubes may be introduced one at a time into the system for closed tube sampling. Positive tube identification can be achieved with an optional barcode scanner. An aliquot volume sufficient for all tests ordered is transferred and stored and the closed tube is returned to the user. • Sample cups are introduced to the system one at a time or by sample ring segment. • Disposable cuvettes are loaded in bulk and then automatically injected as needed by a cuvette hopper system. The ACE Axcel Clinical Chemistry System optical system is capable of monitoring a maximum of 48 cuvettes at one time. • The absorbance optical system is capable of absorbance measurements in a linear range of 0.0 to 2.0 absorbance units (at 0.67 cm pathlength).

	Sixteen wavelengths are measured simultaneously using a photodiode array. The ACE HbA1c Reagent is composed of four reagent bottles (Hemoglobin Denaturant, Total Hemoglobin Reagent, HbA1c Agglutinator Reagent and HbA1c Antibody Reagent). The Hemoglobin Denaturant contains: pepsin and buffer (pH 2.4). The Total Hemoglobin Reagent contains: sodium hydroxide (pH 13) and Triton (Octylphenoxypolyethoxyethanol). The HbA1c agglutinator reagent contains: HbA1c hapten covalently attached to a polymer, bovine serum albumin and buffer (pH 2.0). The HbA1c Antibody Reagent contains: HbA1c antibody (mouse) coupled particles, bovine serum albumin and buffer. The ACE CEDIA T Uptake Reagent is composed of two dot-coded, empty reagent bottles for the Enzyme Acceptor (EA) Reagent and the Enzyme Donor (ED) Reagent. These bottles are shrink-wrapped to the Roche Diagnostics Cobas CEDIA T Uptake kit. The EA Reagent contains enzyme acceptor (microbial), 0.111 g/L; phosphate buffer; buffer salts; stabilizers; preservative; detergent. The ED Reagent contains enzyme donor (microbial)-thyroxine conjugate, 0.44 mg/L; *o*-nitro-β-D-galactopyranoside, 3.27 g/L; phosphate buffer; buffer salts; stabilizers; detergent; preservative. The ACE T4 Reagent is composed of two reagent bottles (Antibody/Substrate Reagent and Enzyme Conjugate Reagent). The Antibody/Substrate Reagent (R1) contains: mouse monoclonal anti-thyroxine antibody, 8-anilino-1-naphthalene sulfonic acid, glucose-6-phosphate, nicotinamide adenine dinucleotide and Tris buffer. The Enzyme Conjugate Reagent (R2) contains: glucose-6-phosphate dehydrogenase labeled with thyroxine and Tris buffer. The ACE Ferritin Reagent is composed of two dot-coded, empty reagent bottles for the Ferritin Buffer and the Ferritin Antibody Reagent. The Ferritin Buffer (R1) contains a glycine buffer. The Ferritin Antibody Reagent (R2) contains a suspension of latex particles sensitized with rabbit anti-human ferritin antibody. These bottles are shrink-wrapped to the Kamiya Biomedical Ferritin kit.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

ALFA WASSERMANN Diagnostic Technologies, LLC
c/o Hyman Katz, PhD
4 Henderson Drive
West Caldwell, NJ 07006

AUG 6 2012

Re: k113437
Trade Name: ACE Hemoglobin A1c (HbAlc) Reagent
ACE CEDIA T Uptake Reagent
ACE T4 Reagent
ACE Ferritin Reagent

Regulation Number: 21 CFR §864.7470
Regulation Name: Glycosylated hemoglobin assay
Regulatory Class: Class II
Product Codes: LCP, KHQ, KLI, DBF
Dated: July 30, 2012
Received: July 31, 2012

Dear Dr Katz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K113437

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Indications for Use: ACE Hemoglobin A1c (HbA1c) Reagent is intended for the quantitative determination of hemoglobin A1c (µmol/L) and total hemoglobin (g/dL) in human EDTA whole blood for the calculation of percent hemoglobin A1c using the ACE Axcel Clinical Chemistry System. The test is intended for use in clinical laboratories or physician office laboratories to monitor long term blood glucose control in individuals with diabetes mellitus. For *in vitro* diagnostic use only.

Prescription Use X (21 CFR Part 801 Subpart D) AND/OR Over-The-Counter Use. (21 CFR Part 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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Indications for Use

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Device Name: ACE CEDIA T Uptake Reagent

Indications for Use: The ACE CEDIA T Uptake homogenous enzyme immunoassay is intended for the quantitative determination of unoccupied binding sties of thyroxine-binding proteins in serum using the ACE Axcel Clinical Chemistry System. Measurements of triiodothyronine uptake are used in the diagnosis and treatment of thyroid disorders. This test is intended for use in clinical laboratories or physician office laboratories. For in vitro diagnostic use only.

Device Name: ACE T4 Reagent

Indications for Use: The ACE T4 Reagent is intended for the quantitative determination of total thyroxine (T4) concentration in serum using the ACE Axcel Clinical Chemistry System. Total thyroxine measurements are used in the diagnosis and treatment of thyroid diseases. This test is intended for use in clinical laboratories or physician office laboratories. For in vitro diagnostic use only.

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